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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,632	11/09/2005	Yves Rayssiguier	1487-27	4695
23117 7590 05/14/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
			EXAMINER CRANE, LAWRENCE E	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 05/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,632

Applicant(s)

RAYSSIGUIER ET AL.

Examiner

L. E. Crane

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/16/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

The Abstract of the Disclosure is objected to because it does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

The instant Abstract is too brief and fails to further define the terms "oxidative stress" and "prebiotics." Amendment to address these issues is respectfully requested.

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

No claims have been cancelled, claims 1-9 have been amended, the disclosure has been amended at page 1, and no new claims have been added as per the preliminary amendment filed June 16, 2005. One Information Disclosure Statement (1 IDS) filed June 16, 2005 has been received with all cited references and made of record.

Claims 1-10 remain in the case.

Note to applicant: when a rejection refers to a claim X at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Claims 1-3 are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See

for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App., 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

Applicant is referred to claims 1-3 at line 2 wherein the term “use” is found. Examiner suggests substitution of other terminology that does not imply a process step or other appropriate action.

Claims 1, 4-6 and 8-9 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the noted claims the terms “prevention,” “anti-radical effect,” and “anti-ageing” imply an effect or effects not adequately demonstrated by the written description of the instant disclosure. Therefore, applicant is respectfully requested to delete the noted terms or to substitute therefore by amendment terminology that is adequately supported by the written description.

Claim 2 is objected to because of the following informalities:

Claim 2 lacks terminal punctuation.

Appropriate correction is required.

Claims 1, 2, 4-7 and 10 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 at lines 1-2, the term “oxidative stress” is defined in Taber’s Cyclopedic Medical Dictionary (PTO-892 ref. R) as “[t]he cellular damage caused by oxygen-derived free radical formation ... [wherein the] three most important are superoxide, hydrogen peroxide, and hydroxyl radicals, [species] produced during normal metabolic processes as well as in reaction to cell injury ... [t]he extend of their damaging potential can be decreased by antioxidants.” In light of the absence of a showing that any one of the listed substances in claim 2 are effective free radical traps, e.g. “antioxidants,” examiner doubts that the instant claim is properly defined when the term “treating oxidative stress” is present. Alternatively, applicant appears to be

claiming a method of treatment related to the over-consumption of glucose or substances readily converted to glucose (e.g. sucrose, starch, etc.) or possibly diseases wherein glucose is no longer properly metabolized, e.g. -- diabetes --. Clarification by amendment and/or explanation is respectfully requested.

Alternatively, the preamble of claim 1 is misleading because the subject matter of claim 1 and claims 4-6 suggests that what is actually being treated is -- over-consumption of monosaccharides --.

In claim 2, line 2, the term "chosen from" is not Markush terminology and the subsequent list is not separated by appropriate punctuation and the last two members of the Markush group are not separated by the term -- and --. Applicant is respectfully requested to amend the noted term to read -- selected from A, B, C, and X -- or to introduce the complete classical Markush format; e.g. -- selected from the group consisting of [A], [B], ... and [R] --.

In claim 7 at lines 3 and 4, applicant has included more than one range of daily dosage but has failed to separate these by the term -- or --- to indicate that these different ranges are alternatives. To insure clarity examiner suggests insertion of the term -- or -- between the three alternatives.

In claim 10 at line 2, the term "'as defined in claim 3" is superfluous because the subject matter following this term entirely defines the mixture of substances being claimed. In addition, the noted term renders the claim improperly dependent because a composition claim cannot properly depend from a method of treatment claim. Examiner suggests deletion of the cited term as one possible solution.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

Claims 1-10 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Van Loo et al.** (PTO-892 ref. U) in view of **Beers et al.** (PTO-892 ref. X, excerpt from The Merck Manual).

The instant claims are directed to mixtures of fructose and fructooligosaccharides (FOS) in a food composition wherein the proportions of these two components can vary widely, and the administration of said compositions to treat “oxidative stress,” aka over consumption of fructose and/or other quickly metabolizable monosaccharides wherein the overconsumption is alleged by the claims to be associated with ageing as a consequence of an increase in free-radical generation in vivo as a consequence of monosaccharide overconsumption.

Van Loo et al. discloses at page 535, column 1 that inulin and fructooligosaccharides (FOS) are not adsorbed from the mammalian intestine and therefore their only food value is a consequence of the heat generated by their subsequent partial consumption by intestinal flora in the latter portion of the small intestine. **Van Loo et al.** also discloses at Tables 1, 6, 9 and 10 numerous different food compositions containing mixtures of varying proportions of fructose and FOS, and also teaches at page 540, column 1 (paragraph beginning with “Literature Data”), that the relative proportions of fructose and FOS can be adjusted by heating (roasting). At pages 536-546 this reference lists a variety of food stuffs wherein FOS is a naturally occurring component part. At page 550, column 1, second full paragraph, this reference also discloses that the average U.S. human consumptions of fructose and FOS intake are 7 grams/day and 7-20 grams/day, respectively.

Van Loo et al. does not expressly disclose the precisely limiting proportions of fructose and FOS to be present in a food composition or disclose that consumption of greater proportions of FOS relative to fructose has health benefits associated with a reduction of “oxidative stress,” aka over production of free radicals or other consequences of the over consumption of monosaccharides including fructose.

Beers et al. discloses at pages 58-62 that obesity is a major cause of health problems and at page 61 (Prognosis and Treatment) counsels the necessity of reducing caloric intake as an essential part of effectively treating this problem. This reference does not mention the details of food compositions, but does mention limitation of caloric intake as a measure used by weight management programs to reduce weight over time.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to reduce the ill-effects of the over consumption of readily adsorbed monosaccharides (overweight, high blood sugar, high blood lipid levels, high blood pressure, atherosclerosis, etc.) by the reduction of the proportion of these substances in food compositions, including by adoption of food compositions of the kinds disclosed in **Van Loo et al.** wherein inulin and associated fructooligosaccharide mixtures (FOS) are present along with monosaccharides including fructose in both naturally occurring and processed food compositions. The introduction of mechanistic explanations wherein terms like "oxidative stress" are presented does not change the well established fact that over consumption of food compositions causes health problems, and that reduction of this consumption, including reduction of the consumption of monosaccharides like fructose, is one step the ordinary practitioner can take to avoid one or more of the negative medical consequences listed above. The **Beers et al.** reference confirms this view.

Therefore, the instant claimed fructose plus fructooligosaccharide (FOS) food compositions and the effect of the administration of these compositions as part of a calorie restricted diet, wherein the total quantity of monosaccharides consumed by the host being treated for "oxidative stress" (aka over consumption of monosaccharides) is reduced, would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

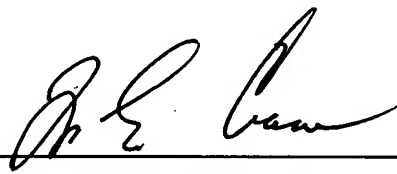
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
05/10/2007

A handwritten signature in black ink, appearing to read 'L. E. Crane', is written over a horizontal line.

L. E. Crane, Ph.D., Esq.
Patent Examiner
Technology Center 1600